IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC and FOREST LABORATORIES HOLDINGS, LTD.,	)	
Plaintiffs,	)	
	)	C.A. No. 14-1119 (SLR-SRF)
v.	)	CONSOLIDATED
SIGMAPHARM LABORATORIES, LLC, et al.,	)	C.A. No. 15-0158 (SLR-SRF)
	)	C.A. No. 15-0430 (SLR-SRF)
Defendants.	)	C.A. No. 14-1504 (SLR-SRF)
	)	C.A. No. 14-1266 (SLR-SRF)

[~~PROPOSED~~ SLR] FINAL JUDGMENT

This action having been tried before the Court from October 24 through November 3, 2016, with the Honorable Sue L. Robinson Senior District Judge presiding, the evidence and testimony of witnesses of each side having been heard and a decision having been rendered:

IT IS HEREBY ORDERED AND ADJUDGED this 14th day of July, 2017, for the reasons set forth in the opinion dated June 30, 2017 (D.I. 322), and the prior stipulations entered into between the parties (D.I. 102, 174, 178, 181, 183, 238, 287, and 279), that final judgment be and is hereby entered as follows:

Amneal Defendants

1. Judgment entered in favor of Plaintiffs Forest Laboratories, LLC (f/k/a/ Forest Laboratories, Inc.) and Forest Laboratories Holdings, Ltd. (collectively, "Plaintiffs"), and against Defendants Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India Pvt. Ltd. (collectively "Amneal") on Plaintiffs' Counts I and II in their "Complaint for Patent Infringement," dated May 28, 2015 (D.I. 1, 15-cv-0430), that Amneal, pursuant to 35 U.S.C. §§ 271(a)–(c) and (e)(2), has infringed claims 1, 2, 5, and 6 of

U.S. Patent No. 5,763,476 (the "'476 Patent") by submitting to the FDA ANDA No. 207307 that seeks approval to commercially market, before the expiration of the '476 Patent, Amneal's generic asenapine product—the manufacture, use, and sale of which would directly infringe the asserted claims of the '476 Patent, and the sale of which would contribute to and induce the infringement of the asserted claims of the '476 Patent by users of Amneal's generic asenapine product;

2. Judgment entered in favor of Plaintiffs and against Defendants Amneal on Plaintiffs' Counts I and II in their "Complaint for Patent Infringement," dated May 28, 2015 (D.I. 1, 15-cv-0430), that Amneal, pursuant to 35 U.S.C. §§ 271(b)–(c) and (e)(2), will induce and contribute to the infringement of claims 4, 9, and 10 of the '476 Patent by selling Amneal's generic asenapine product in the United States with labeling containing schizophrenia as an indication; and

3. Judgment entered in favor of Plaintiffs and against Amneal, on all of Amneal's Counterclaims set forth in its "Answer and Counterclaims of Amneal Pharmaceuticals, LLC Amneal Pharmaceuticals of New York, LLC and Amneal Pharmaceuticals Co. India PVT. Ltd.," dated August 3, 2015 (D.I. 13 in C.A. No. 15-430), alleging noninfringement and invalidity of the asserted claims of the '476 Patent; and

4. Judgment entered in favor of Plaintiffs and against Amneal, that claims 1, 2, 4, 5, 6, 9, and 10 of the '476 Patent are valid.

IT IS HEREBY ORDERED that, under 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Amneal's ANDA No. 207307 is to be a date not earlier than the date of the expiration of the '476 Patent inclusive of the patent term extension granted under 35 U.S.C. § 156 and any applicable adjustments, extensions, and exclusivities (including

pediatric exclusivity) to which Plaintiffs are or become entitled (all inclusively "the '476 Patent Term")[1], except to the extent subsequently agreed between Plaintiffs and Amneal;

and it is further **ORDERED** that, Amneal, and all persons acting in concert with Amneal, are enjoined from obtaining or maintaining final approval of ANDA No. 207307 until the expiration of the '476 Patent Term, except to the extent subsequently agreed between Plaintiffs and Amneal;

and it is further **ORDERED** that, under 35 U.S.C. § 271(e)(4)(B), Amneal and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them are enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Amneal's proposed generic asenapine maleate product that is the subject of Amneal's ANDA No. 207307 during the '476 Patent Term. This injunction is effective as of the Court's June 30, 2017 Order;

and it is further **ORDERED**, that this judgment entry is certified and entered by the Court pursuant to Rule 54(b) of the Federal Rules of Civil Procedure as final judgment on all claims adjudicated, and that there is no just reason for delay.

Hikma Defendants

1. Judgment entered in favor of Plaintiffs and against Defendants Hikma Pharmaceuticals, LLC, Hikma Pharmaceuticals, PLC, and West-Ward Pharmaceutical Corp. (collectively "Hikma") on Plaintiffs' Counts V and VI in their "Amended Complaint for Patent Infringement," dated February 2, 2015 (D.I. 22 in C.A. No. 14-1266), that Hikma, pursuant to 35 U.S.C. §§ 271(a)–(c) and (e)(2), has infringed claims 1, 2, 5, and 6 of the '476 Patent by submitting to the FDA ANDA No. 206117 that seeks approval to commercially market, before

[1] For the purpose of the Final Judgment, the term "the '476 Patent Term," as used throughout the entirety of the Final Judgment, applies only to the claims at issue in this litigation, i.e., claims 1, 2, 4, 5, 6, 9, and 10 of the '476 patent.

the expiration of the '476 Patent Term, Hikma's generic asenapine product—the manufacture, use, and sale of which would directly infringe the asserted claims of the '476 Patent, and the sale of which would contribute to and induce the infringement of the asserted claims of the '476 Patent by users of Hikma's generic asenapine product;

2. Judgment entered in favor of Plaintiffs and against Defendants Hikma on Plaintiffs' Counts V and VI in their "Amended Complaint for Patent Infringement," dated February 2, 2015 (D.I. 22 in C.A. No. 14-1266), that Hikma, pursuant to 35 U.S.C. §§ 271(b)–(c) and (e)(2), will induce and contribute to the infringement of claims 4, 9, and 10 of the '476 Patent by selling Hikma's generic asenapine product in the United States with labeling containing schizophrenia as an indication; and

3. Judgment entered in favor of Plaintiffs, and against Hikma, that claims 1, 2, 4, 5, 6, 9, and 10 of the '476 Patent are valid.

4. This Final Judgment does not supersede the Court's "Joint Stipulation of Entry and Order of Adverse Judgment and Dismissal of Counterclaims of U.S. Patent Nos. 7,741,358 and 8,022,228" (D.I. 174 in C.A. No. 1:14-cv-1119).

IT IS HEREBY ORDERED that, under 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Hikma's ANDA No. 206117 is to be a date not earlier than the date of the expiration of the '476 Patent Term except to the extent subsequently agreed between Plaintiffs and Hikma;

and it is further **ORDERED** that, Hikma, and all persons acting in concert with Hikma, are enjoined from obtaining or maintaining final approval of ANDA No. 206117 until the expiration of the '476 Patent Term, except to the extent subsequently agreed between Plaintiffs and Hikma;

and it is further **ORDERED** that, under 35 U.S.C. § 271(e)(4)(B), Hikma and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them are enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Hikma's proposed generic asenapine maleate product that is the subject of Hikma's ANDA No. 206117 during the term of the '476 Patent Term. This injunction is effective as of the Court's June 30, 2017 Order;

and it is further **ORDERED**, that this judgment entry is certified and entered by the Court pursuant to Rule 54(b) of the Federal Rules of Civil Procedure as final judgment on all claims adjudicated, and that there is no just reason for delay.

Alembic Defendants

1. Judgment entered in favor of Plaintiffs and against Defendants Alembic Pharmaceuticals Ltd., Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively "Alembic"), with respect to the infringement of claims 1, 2, 5, and 6 of the '476 Patent on Plaintiffs' Counts I and II in their "Complaint for Patent Infringement," dated February 13, 2015 (D.I. 1 in C.A. No. 15-158), that Alembic, pursuant to 35 U.S.C. §§ 271(a) and (e)(2), has infringed claims 1, 2, 5, and 6 of the '476 Patent by submitting to the FDA ANDA No. 206098 that seeks approval to commercially market, before the expiration of the '476 Patent Term, Alembic's generic asenapine product—the manufacture, use, and sale of which would directly infringe the asserted claims of the '476 Patent;

2. Judgment entered in favor of Alembic and against Plaintiffs on Plaintiffs' Counts I and II in their "Complaint for Patent Infringement," dated February 13, 2015 (D.I. 1 in C.A. No. 15-158), with respect to claims 4, 9, and 10 of the '476 Patent, that Alembic, pursuant to 35 U.S.C. §§ 271(b)–(c) and (e)(2), has not infringed claims 4, 9, and 10 of the '476 Patent by submitting to the FDA ANDA No. 206098, as amended to remove schizophrenia as an

indication, that seeks approval to commercially market, before the expiration of the '476 Patent Term, Alembic's generic asenapine product;

3. Judgment entered in favor of Plaintiffs and against Alembic, that claims 1, 2, 4, 5, 6, 9, and 10 of the '476 Patent are valid;

IT IS HEREBY ORDERED that, under 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Alembic's ANDA No. 206098 is to be a date not earlier than the date of the expiration of the '476 Patent Term, except to the extent subsequently agreed between Plaintiffs and Alembic;

and it is further **ORDERED** that, Alembic, and all persons acting in concert with Alembic, are enjoined from obtaining or maintaining final approval of ANDA No. 206098 until the expiration of the '476 Patent Term, except to the extent subsequently agreed between Plaintiffs and Alembic;

and it is further **ORDERED** that, under 35 U.S.C. § 271(e)(4)(B), Alembic and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them are enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Alembic's proposed generic asenapine maleate product that is the subject of Alembic's ANDA No. 206098 during the '476 Patent Term. This injunction is effective as of the Court's June 30, 2017 Order;

and it is further **ORDERED**, that this judgment entry is certified and entered by the Court pursuant to Rule 54(b) of the Federal Rules of Civil Procedure as final judgment on all claims adjudicated, and that there is no just reason for delay.

Breckenridge

1. Judgment entered in favor of Plaintiffs and against Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge"), with respect to the infringement of claims 1, 2, 5, and 6

of the '476 Patent, on Plaintiffs' Counts I and II in their "Complaint for Patent Infringement," dated December 22, 2014 (D.I. 1 in C.A. No. 14-1504), and on Breckenridge's Counterclaim I alleging noninfringement of the '476 Patent set forth in its "Amended Answer, Affirmative Defenses, and Counterclaims of Defendant Breckenridge Pharmaceutical, Inc.," dated January 20, 2015 (D.I. 14 in C.A. No. 14-1504), that Breckenridge, pursuant to 35 U.S.C. §§ 271(a) and (e)(2), has infringed claims 1, 2, 5, and 6 of the '476 Patent by submitting to the FDA ANDA No. 205960 that seeks approval to commercially market, before the expiration of the '476 Patent Term, Breckenridge's generic asenapine product—the manufacture, use, and sale of which would directly infringe the asserted claims of the '476 Patent;

2. Judgment entered in favor of Breckenridge and against Plaintiffs, with respect to claims 4, 9, and 10 of the '476 Patent, on Plaintiffs' Counts I and II in their "Complaint for Patent Infringement," dated December 22, 2014 (D.I. 1 in C.A. No. 14-1504), and on Breckenridge's Counterclaim I alleging noninfringement of the '476 Patent set forth in its "Amended Answer, Affirmative Defenses, and Counterclaims of Defendant Breckenridge Pharmaceutical, Inc.," dated January 20, 2015 (D.I. 14 in C.A. No. 14-1504), that Breckenridge, pursuant to 35 U.S.C. §§ 271(b)–(c) and (e)(2), has not infringed claims 4, 9, and 10 of the '476 Patent by submitting to the FDA ANDA No. 205960, as amended to remove schizophrenia as an indication, that seeks approval to commercially market, before the expiration of the '476 Patent Term, Breckenridge's generic asenapine product;

3. Judgment entered in favor of Plaintiffs and against Breckenridge on Breckenridge's Counterclaim II alleging invalidity of the '476 Patent, set forth in its "Amended Answer, Affirmative Defenses, and Counterclaims of Defendant Breckenridge Pharmaceutical, Inc.," dated January 20, 2015 (D.I. 14 in C.A. No. 14-1504);

4. Judgment entered in favor of Plaintiffs and against Breckenridge, that claims 1, 2, 4, 5, 6, 9, and 10 of the '476 Patent are valid; and

5. This Final Judgment does not supersede the Court's "Judgment of Non-Infringement and Order of Dismissal of Counterclaims" (D.I. 178 in C.A. No. 1:14-cv-1119).

IT IS HEREBY ORDERED that, under 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the FDA of Breckenridge's ANDA No. 205960 is to be a date not earlier than the date of the expiration of the '476 Patent Term, except to the extent subsequently agreed between Plaintiffs and Breckenridge;

and it is further **ORDERED** that, Breckenridge, and all persons acting in concert with Breckenridge, are enjoined from obtaining or maintaining final approval of ANDA No. 205960 until the expiration of the '476 Patent Term, except to the extent subsequently agreed between Plaintiffs and Breckenridge;

and it is further **ORDERED** that, under 35 U.S.C. § 271(e)(4)(B), Breckenridge and its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them are enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Breckenridge's proposed generic asenapine maleate product that is the subject of Breckenridge's ANDA No. 205960 during the '476 Patent Term. This injunction is effective as of the Court's June 30, 2017 Order;

and it is further **ORDERED**, that this judgment entry is certified and entered by the Court pursuant to Rule 54(b) of the Federal Rules of Civil Procedure as final judgment on all claims adjudicated, and that there is no just reason for delay.

Sigmapharm

1. Judgment entered in favor of Plaintiffs and against Sigmapharm Laboratories LLC ("Sigmapharm") on Sigmapharm's Counterclaim II, alleging invalidity of the '476 Patent,

set forth in its "Answer, Affirmative and Separate Defenses and Counterclaims to Plaintiffs' Amended Complaint," filed May 22, 2017 (D.I. 307 in C.A. No. 14-1119);

2. Judgment entered in favor of Plaintiffs and against Sigmapharm, that claims 1, 2, 4, 5, 6, 9, and 10 of the '476 Patent are valid;

3. This Final Judgment does not supersede the Court's "Order Staying Trial as to Sigmapharm's Infringement of Claims 1, 2, 4, 5, 6, 9, and 10 of U.S. Patent No. 5,763,476 and Extension of 30-Month Stay" (D.I. 278 in C.A. No. 1:14-cv-01119); and

4. This Final Judgment does not supersede the Court's "Joint Stipulation of Entry and Order of Adverse Judgment and Dismissal of Counterclaims of U.S. Patent Nos. 7,741,358 and 8,022,228" (D.I. 181 in C.A. No. 1:14-cv-1119).

IT IS HEREBY ORDERED that this judgment entry is certified and entered by the Court pursuant to Rule 54(b) of the Federal Rules of Civil Procedure as final judgment on all claims adjudicated, and that there is no just reason for delay.

Pursuant to Delaware Rules 54.1 and 54.3, any of the parties to this Final Judgment may, within 14 days after the time for appeal has expired or within 14 days after the issuance of the mandate of the appellate court, file a bill of costs and any motion requesting attorney fees.

SO ORDERED this 11th day of July, 2017

United States District Judge

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